DETAILED ACTION

Specification

1. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet **within the range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
(f) BACKGROUND OF THE INVENTION.
    (1) Field of the Invention.
    (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Armstrong et al. (6,899,727) in view of Susawa et al. (5,591,222).

Claim 1:

Armstrong discloses a device (10) for delivery of a stent (12) for the vessel (20) comprising: a catheter (16) for insertion into the vessel (20) of a living body (Fig. 1); a balloon (15) mounted on an outer peripheral surface of the distal end side of said catheter (Fig. 1) and inflatable with a fluid supplied to said catheter (Fig. 1-1B); a stent (12) for the vessel mounted on said balloon in a diameter-contracted state (Fig. 1A and Col. 6 Lines 32-38), said stent having self-expanding properties (Col. 3 Lines 1-5 and Col. 6 Lines 47-48); and a stent holding member (11) formed of a polymer material (Col. 3 Lines 3-6) to a tube form (Fig. 1) for holding said stent for the vessel on said balloon (Fig. 1 and Col. 3 Lines 3-6), and configured for covering at least a portion of said stent for the vessel from said catheter (Fig. 1 and 6A); said stent holding member having been drawn in the longitudinal direction (Fig. 1-1B) and being provided with a tearing assisting portion (19) at a distal end thereof located towards the distal end of said catheter (Fig. 1, 5, 6, 11).

Armstrong teaches all the claimed limitations discussed above however, Armstrong does not disclose that the stent is formed of a biodegradable polymer

Susawa discloses said stent (1) being formed of a biodegradable polymer (Col. 2 Lines 59-61).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Armstrong with a biodegradable stent in view of the

teachings of Susawa, in order to provide a stent that would not have to be later removed from the body after vessel repair. Further, the combination would have merely required a substitution of one stent for another. It has been held that the substitution of one known element for another to yield predictable results requires only routine skill in the art.

Additionally, i would have been obvious to one having ordinary skill in the art at the time the invention was made to use a biodegradable material on the stent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 2: Armstrong discloses that said tearing assisting portion is a slit (each perforation 19 is a slit as seen in Fig. 1, 5, 6) provided to the distal end side of said stent holding member (Fig. 1).

Claim 3: Armstrong discloses that the distal end of said tearing assisting portion is closed by a connecting portion (Fig. 1, 5, 6).

Claim 4: Armstrong discloses that said tearing assisting portion is a slit formed for extending along the drawing direction of said stent holding member (Fig. 1, 5, 6).

Claim 5: Armstrong discloses that said stent holding member is formed of PTFE (polytetrafluoroethylene) (Col. 3 Line 6).

Claim 6: Armstrong discloses that the proximal side of said stent holding member, located on said catheter, is secured to said catheter)Col. 4 Lines 60-65).

Claim 7: Armstrong discloses that an air-vent through-hole is bored in the proximal side of said stent holding member secured to said catheter (Fig. 1-2 where the stent holding member has a lumen/bore through its center where the stent is located).

Claim 8: Armstrong discloses that said stent holding member covers up the entire length of said stent for the vessel (Fig. 1, 5, 6).

Claim 9: Armstrong discloses that the distal end of said stent holding member, provided with said tearing assisting portion, is contracted in diameter so as to be tightly contacted with said balloon (Fig. 1, 5, 6 where it is contracted when assembled prior to delivery).

Claim 10: Armstrong discloses that said stent holding member is connected to a yarn (111) passed through said catheter so as to be pulled out partway from said catheter, and wherein said stent holding member may be released from the stent for the vessel by pulling said yarn outward from said catheter (Fig. 11 and Col. 9 Lines 45-64).

Claim 11:

Armstrong teaches all the claimed limitations discussed above however, Armstrong does not disclose that the stent is formed of a yarn of a biodegradable polymer to a tube form.

Susawa discloses said stent (1) being formed of a yarn of biodegradable polymer (Col. 2 Lines 42-61).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide Armstrong with a yarn of a biodegradable polymer to form the stent in view of the teachings of Susawa, in order to provide a stent that would not have to be later removed from the body after vessel repair. Further, the combination

would have merely required a substitution of one stent for another. It has been held that the substitution of one known element for another to yield predictable results requires only routine skill in the art.

Additionally, i would have been obvious to one having ordinary skill in the art at the time the invention was made to use a biodegradable material on the stent, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Note that the claimed phrase "formed of a yarn biodegradable polymer to a tube form" is being treated as a product by process limitation. As set forth in MPEP 2113, product by process claims are not limited to the manipulation of the recited steps, only the structure implied by the steps. Once a product appearing to be substantially the same or similar is found, a 35 USC 102/103 rejection may be made and the burden is shifted to applicant to show an unobvious difference. MPEP 2113.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANNE DORNBUSCH whose telephone number is (571)270-3515. The examiner can normally be reached on Monday through Thursday 7:30 am to 5:00 pm Eastern.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. D./
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773